

2173.05(p) Claim Directed to Product-By- Process or Product and Process

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention.

I. PRODUCT-BY-PROCESS

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process.

An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. *Ex parte Pantzer*, 176 USPQ 141 (Bd. App. 1972).

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph.

Such claims should also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551

diffraction. Either type of evidence would have rebutted the *prima facie* case under 35 U.S.C. 102. A further analysis would be necessary to determine if the process was unobvious under 35 U.S.C. 103.); *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to *Dart* disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. *Dart* was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.).

PROCESS OF USE CLAIMS — NEW AND UNOBVIOUS USES OF OLD STRUCTURES AND COMPOSITIONS MAY BE PATENTABLE

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7-10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. “While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition.” 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).

2113 [R-1] Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added,

but is instead produced in-situ does not change the end product.).

>The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding “interbonded by interfusion” to limit structure of the claimed composite and noting that terms such as “welded,” “intermixed,” “ground in place,” “press fitted,” and “etched” are capable of construction as structural limitations.)<

ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS FOUND AND A 35 U.S.C. 102 /103 REJECTION MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBTAINABLE DIFFERENCE

“The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature” than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobtainable difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be “essentially free of alkali metal.” The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not “essentially free of alkali metal” and therefore a different and unobtainable product.).

Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobtainable difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

THE USE OF 35 U.S.C. 102 /103 REJECTIONS FOR PRODUCT-BY-PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

“[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535,

(b)

--the process as claimed can be practiced by hand--,

(c)

--the apparatus as claimed can be used to practice another and materially different process such as--.

3.

Conclude restriction requirement with one of form paragraphs 8.21.01 through 8.21.03.

The burden is on the examiner to provide reasonable examples that recite material differences.

If the apparatus claims include a claim to “means” for practicing the process, this claim is a linking claim (except for the presence of this claim restriction between apparatus and process claims would be proper). The linking claim must be examined with the elected invention, but only to the extent necessary to determine if the linking claim is unpatentable. If the linking claim is unpatentable, restriction is proper.

It should be noted that a claim such as, “An apparatus for the practice of the process of claim 1, comprising” and then the claim continues with purely apparatus limitations, is not a linking claim. This is merely a preamble similar to a statement of intended use and should be treated as any preamble.

If applicant proves or provides convincing argument that there is no material difference or in the case of a process that cannot be performed by hand (if examiner so argued), the burden is on the examiner to document another materially different process or apparatus or withdraw the requirement.

806.05(f) Process of Making and Product Made — Distinctness

A process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process *as claimed* is not an obvious process of making the product and the process *as claimed* can be used to make other and different products; or (B) that the product *as claimed* can be made by another and materially different process.

Allegations of different processes or products need not be documented.

A product defined by the process by which it can be made is still a product claim (*In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)) and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process; defining the product in terms of a process by which it is made is nothing more than a permissible technique that applicant may use to define the invention.

If applicant convincingly traverses the requirement, the burden shifts to the examiner to document a viable alternative process or product, or withdraw the requirement.

Form paragraph 8.18 may be used in restriction requirements between product and process of making.

¶ 8.18 Product and Process of Making

Inventions [1] and [2] are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case [3].

Examiner Note

1.

This form paragraph is to be used when claims are presented to both a **product** and the **process of making** the product (MPEP § 806.05(f)).

2.

In bracket 3, use one or more of the following reasons:

(a)

--the process as claimed can be used to make a materially different product such as

.....--,

(b)

--the product as claimed can be made by a materially different process such as--.

3.

Conclude restriction requirement with one of form paragraphs 8.21.01 through 8.21.03.